

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2012798	(X3) Date Survey Completed 09/23/2024
Name of Provider or Supplier West Cancer Center	Street Address, City, State 1290 Kelley Dr, Paris, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on a review of calibration records, patient test reports, and staff interview, the laboratory failed to verify the calibration of the Magnesium analyte at least every six months in 2023 and 2024. The findings include: 1. A review of the calibration records for the Ortho Vitros 350 chemistry instrument revealed that Magnesium was not calibrated every six months as follows: Performed on 06/21/23-calibration was not performed in December 2023. Performed on 01/09/24. No other calibrations for the</p>

	<p>Magnesium analyte had been performed by the survey date (09/23/24). 2. A review of a patient test report revealed Magnesium reported on patient 578074 on 09/23/24 when the six-month calibration verification requirement for the Magnesium analyte had not been met. 3. During an interview on 09/23/24 at 4:00 p.m., the technical consultant confirmed the laboratory failed to verify the calibration of the Magnesium analyte every six months in 2023 and 2024.</p>
<p>D5469</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory observation, review of the laboratory's Complete Blood Count with automated White Blood Cell (WBC) Differential (CBC w/Diff) quality control (QC) records, final patient test reports, and staff interview, the laboratory failed to establish QC ranges for the Red Cell Distribution Width (RDW) and Mean Platelet Volume (MPV) for nine of nine lots reviewed from 2023 and 2024 with patient testing reported. The findings include: 1. Laboratory observation on 09/24/24 at 8:30 a. m. revealed Cell Dyn Emerald instruments (serial numbers 377 and 599) used for performing patient testing for CBC w/Diff. 2. A review of the laboratory's CBC w /Diff QC records revealed the following: QC lot number 3205 (low, normal, and high) was used from 09/11/23 to 11/09/23. QC lot number 3317 (low, normal, and high) was used from 12/28/23 to 02/29/24. QC lot number 4120 (low, normal, and high) was used beginning 06/20/24 with an expiration date of 08/16/24. The assigned assay value for both RDW and MPV were 49.9 with a limit of 49.9 resulting in a QC range of 0 - 99.8 for all nine lots. 3. A review of the manufacturer's quality control package inserts for lots 3205, 3317 and 4120 revealed the manufacturer did not provide QC ranges for the RDW and MPV analytes. 4. A review of patient test results revealed that RDW and MPV were reported on patient numbers 627573 on 10/27/23, 565748 on 02/14/24, and 613891 on 07/17/24 during the period when the laboratory did not have QC ranges for the RDW and MPV. 5. During an interview on 09/24/24 at 4:00 p. m., the technical consultant confirmed that the manufacturer did not provide QC ranges for the RDW and MPV analytes and the laboratory failed to establish its' own QC ranges.</p>
<p>D5793</p>	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures</p>

necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:

Based on laboratory observation, a review of the laboratory procedure manual, review of calibration records, review of a patient test report, review of the laboratory quality assessment records, and staff interview, the laboratory's quality assessment process was not effective in preventing problems with meeting the six-month calibration requirement for tests performed on the Ortho Vitros 350 instrument (one of nineteen analytes reviewed) from 2023 and 2024. The findings include: 1. Laboratory observation on 09/23/24 at 8:30 a.m. revealed the Ortho Vitros 350 (serial number J27005000) used for patient testing for chemistry analytes. 2. A review of the laboratory procedure manual revealed that calibration is performed every six months or each new lot for tests performed on the Ortho Vitros 350 chemistry instrument. 3. A review of calibration records revealed the following: Magnesium calibration was performed on 06/21/23 and again on 01/09/24. No other calibrations had been performed by the survey date (09/23/24). The six-month requirement was not met when calibration was not performed in December 2023 or in July 2024. 4. A review of patient number 578074 revealed Magnesium reported on 09/23/24 during the period when the six-month calibration had not been performed. 5. A review of the laboratory's monthly quality assessment documentation revealed that the problem with performing calibrations at least every six months was identified in January 2024 with documented corrective action. 6. A review of the monthly quality assessment reviews from February 2024 to August 2024 revealed no evidence of continued monitoring to ensure the corrective action was effective. 7. The technical consultant confirmed during an interview on 09/23/24 at 4:00 p.m. that the laboratory's quality assessment process was not effective in correcting and preventing future problems with performing six-month calibrations.

D5801

TEST REPORT

CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on laboratory observation, review of an instrument printout and final test report, review of the laboratory procedure manual, review of the Cell Dyn Emerald operators manual, and staff interview, the laboratory information system (LIS) failed to hold results that were flagged by the instrument (potentially since 05/22/24), resulting in the reporting of patient CBC w/Diff results without corrective action as required by laboratory procedure for one of one patients reviewed with flagged results. The findings include: 1. Laboratory observation on 09/23/24 at 8:30 a.m. revealed Cell Dyn Emerald instruments (serial numbers 377 and 599) used for

performing patient testing for CBC w/Diff. The lead testing person stated during observation that the laboratory used autoverification for patient result transmission. 2. A review of the instrument printout and results in the laboratory LIS for patient number 585942 (performed and reported on 09/23/24) revealed the following: The instrument printout contained flags for L1, L3, and Platelet aggregates. The WBC and WBC differential were flagged with an asterisk (*). There was no evidence of corrective action or repeat testing for the flagged results. The flags did not cross the interface into the patient electronic medical record. The results were reported in the patient chart. 3. A review of the laboratory's policy titled "MANUAL DIFFERENTIAL POLICY" revealed that if the instrument manufacturer's guidelines required a smear review, slides would be made and sent to a reference laboratory. "The manufacturer's guidelines for manual differentials include but are not limited to: Abnormal WBC flags, Abnormal Platelet flags, Abnormal Hemoglobin, RBC and RBC Indices. LIS rules should hold any abnormalities which will trigger a manual review." 4. A review of the Cell Dyn Emerald operator's manual revealed the following regarding flags: WBC and differential flagged with an asterisk with L1 in the text box: Possible platelet aggregates, erythroblasts, and/or small lymphocytes. Actions to take included checking the specimen for clots or agglutination, retesting after 20 minutes, following the laboratory review criteria or reviewing a stained smear to confirm. Redraw and retest the specimen as required. 5. During an interview on 09/23/24 at 4:00 p.m., the technical consultant confirmed that the laboratory's LIS failed to hold the flagged CBC results for review after a LIS software change, resulting in the reporting of flagged CBC results without laboratory corrective action. 6. During a phone interview on 10/01/24 at 5:10 p.m. the technical consultant stated the autoverification was turned back on sometime after 05/21/24 and stated the Emerald instrument failed to be included in the LIS verification.